Oral Diseases (2005) 11 (Suppl. 1), 51–53

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ORIGINAL ARTICLE

Clinical effectiveness of a triclosan/copolymer/sodium fluoride dentifrice in controlling oral malodor: a 3-week clinical trial

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OBJECTIVE: The purpose of the study was to compare the effectiveness of a dentifrice containing 0.3% triclosan, 2% polyvinylmethylether/maleic acid (PVM/MA) copolymer, 0.243% sodium fluoride (TCF) to a commercially-available dentifrice containing 0.243% sodium fluoride (control) for the management of oral malodor in a 3-week, randomized double-blind, longitudinal clinical trial.

METHODS: A panel of four expert judges used a nine-point hedonic scale to evaluate breath odor using a protocol designed in accordance with the ADA Draft Acceptance Program Guideline for Products Used in the Management of Oral Malodor. Following a baseline evaluation, prospective subjects with hedonic scores above the threshold value for unpleasant breath were stratified by score and randomized into two treatment groups. Subjects brushed their teeth for 1 min with their assigned dentifrice after which they were scored for oral malodor at 1.5, 4 and 12 h. They then used their assigned dentifrice, twice a day, for 3 weeks. Before oral malodor evaluations, the subjects refrained from eating odorigenic foods, using mouthrinses and breath mints and from performing dental hygiene procedures.

RESULTS: Eighty-one adult male and female subjects completed the study. The baseline hedonic scores for the TCF and control dentifrices were 7.80 and 7.84, respectively, corresponding to unpleasant breath. The final mean oral malodor scores for the TCF dentifrice differed significantly from the baseline and control values ($P < 0.05$) for every time point examined (1.5-, 4-, 12-h and 1-, 2- and 3-week intervals). The mean final breath scores for the TCF dentifrice group were 3.06, 3.48, 3.42, 3.66, 3.41 and 3.36, respectively, for each time point. These scores correspond to pleasant breath. Conversely, the control dentifrice group scored at levels either above 5.0 (before 12 h) or above 7.0 (after 12 h) which corresponded to neutral or unpleasant breath.

CONCLUSION: In conclusion, the results of this double-blind clinical study clearly indicate that a dentifrice containing triclosan/copolymer/NaF provides effective control of oral malodor for up to 12 h.
Oral Diseases (2005) **11** (Suppl. 1), 51–53

Keywords: halitosis; triclosan; oral malodor; dentifrice; breath

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Introduction

The objective of this study was to compare the effectiveness of a test dentifrice containing triclosan/copolymer/sodium fluoride to a commercially-available, clinically-proven, ADA-accepted, sodium fluoride control dentifrice for the management of oral malodor in a 3-week, randomized, double-blind, longitudinal clinical trial.

Materials and methods

Products tested

Two commercially-available toothpastes, one containing 0.3% triclosan, 2% copolymer and 0.243% sodium fluoride in a silica base (Colgate-Palmolive Company, New York, USA) and the other containing 0.243% sodium fluoride in a silica base (Colgate-Palmolive Company) were evaluated.

Protocol design

The study employed a double-blind, stratified, two-treatment design, and followed a protocol set forth in the proposed ADA Guidelines for Acceptance of products used for the management of oral malodor (ADA, 2003). Eighty-one adult male and female subjects between 18 and 70 years of age and in good oral and general health took part in the 3-week clinical trial (Table 1). Subjects refrained from all oral hygiene and from eating, drinking and smoking on the morning of the baseline oral malodor examination. The olfactory acuity of a trained four member judge panel was verified

Table 1 Summary of age and sex characteristics of the study participants

	Number of subjects			*Age (years)*	
Dentifrice group	*Male*	*Female*	*Total*	*Mean*	*Range*
TCF-AF	22	19	41	45.12	22–70
Control	21	19	40	44.33	26–68

prior to each evaluation. Oral odor rating was done using a nine-point hedonic scale (1 = most pleasant, 5 = neutral and 9 = most unpleasant). Subjects who presented scores above a threshold value for unpleasant breath odor were stratified by score and randomized into two treatment groups, using the test or control dentifrice. They were instructed to brush their teeth thoroughly in their regular and customary manner for 1 min with their assigned dentifrice.

Odor evaluation

Hedonic scoring of oral malodor was done by four independent, experienced, calibrated judges at 1.5, 4 and 12 h after the first 1-min product use. Subjects were then instructed to brush their teeth twice per day over the next 3 weeks. They returned to the clinical facility on days 8, 15 and 22 for morning appointments, approximately 12 h after their last tooth brushing, and having refrained from eating and drinking, and did not use dental hygiene procedures, breath mints, or mouthrinses. Subjects received the same hedonic oral malodor examination as described above. Following individual scoring, an overall score was determined for each subject by averaging the scores assigned by the four judges.

Statistical analysis

The within-treatment comparisons between the baseline and each time point (1.5 h, 4 h, 12 h, 1 week, 2 weeks and 3 weeks) scores were performed using paired *t*-tests. Comparisons between the study dentifrices with respect to oral malodor scores at baseline and at each test time point after tooth brushing were performed using an analysis of covariance, in which baseline oral malodor was employed as a co-variable. All statistical tests of hypotheses were two-sided, and employed a level of significance of $\alpha = 0.05$.

Results and discussion

There was no statistically significant difference between the mean oral malodor scores for both groups at baseline. The range of values corresponded to *unpleasant* breath. At all measured time points, a statistically significant difference was observed between the triclosan/copolymer/sodium fluoride dentifrice and control dentifrice groups (Tables 2 and 3). The mean malodor scores were within the range corresponding to pleasant breath for the test dentifrice and for the control dentifrice, the values were within the neutral to offensive range (Figures 1 and 2). The percentage of subjects having a reduction of at least a 3.2 unit of their baseline

Table 2 Summary of the daytime breath-odor scores evaluated on day 1 for subjects who completed the clinical study

Dentifrice group	*n*	*Baseline*	*1.5 h*	*4 h*	*12 h*
TCF-AF	41	7.80 ± 0.42	3.06 ± 0.67*	3.48 ± 0.82*	3.42 ± 0.72*
Control	40	7.84 ± 0.39†	5.36 ± 0.65	5.84 ± 0.67	7.03 ± 0.70

*TCF-AF was significantly better than control ($P \leq 0.05$).
†No significant difference between baseline values ($P \geq 0.05$).

Table 3 Summary of the 12-h overnight breath-odor scores at the weekly follow-up evaluation for subjects who completed the clinical study

Dentifrice group	*n*	*Baseline*	*1 Week*	*2 Weeks*	*3 Weeks*
TCF-AF	41	7.80 ± 0.42	3.66 ± 0.50*	3.41 ± 0.53*	3.36 ± 0.50*
Control	40	7.84 ± 0.39†	7.14 ± 0.81	7.16 ± 0.43	7.12 ± 0.34

*TCF-AF was significantly better than control ($P \leq 0.05$).
†No significant difference between baseline values ($P \geq 0.05$).

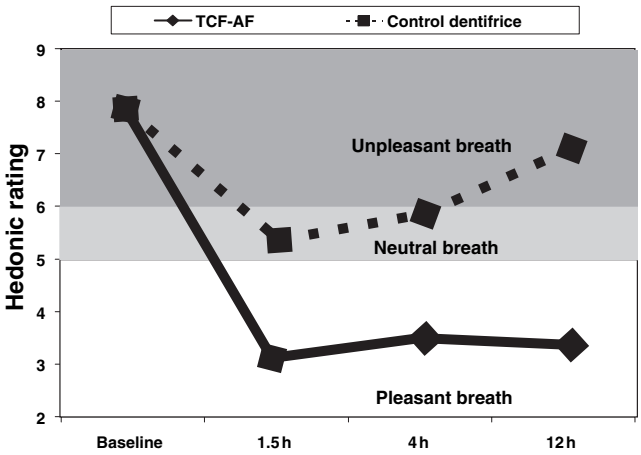

Figure 1 Twelve-hour daytime hedonic scores at day 1 evaluations

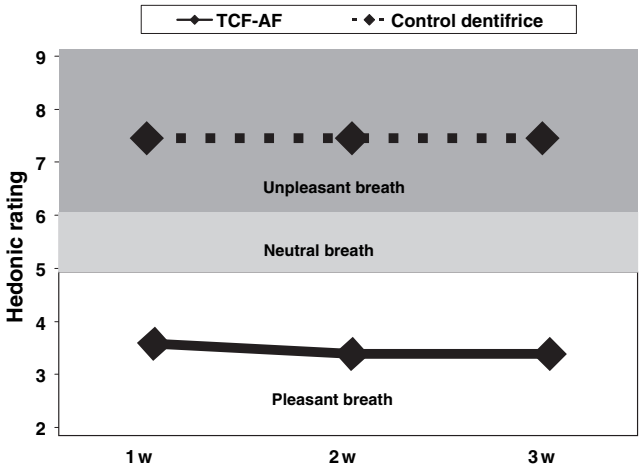

Figure 2 Twelve-hour overnight scores after 3 weeks product use

Table 4 Percentage of subjects exhibiting reduction ≥3.2 units relative to baseline

Dentifrice group	*1.5 h*	*4 h*	*12 h*	*1 Week*	*2 Weeks*	*3 Weeks*
TCF-AF	97.6	87.8	92.7	92.7	95.1	97.6
Control	10.0	10.0	0.0	2.5	0.0	0.0

breath odor scores ranged from 87.8 to 97.6% for the TCF dentifrice and from 0.0 to 10% for the control dentifrice at the measured time points (Table 4).

The copolymer in the triclosan/copolymer/sodium fluoride formula has been shown to enhance the delivery and retention of the antibacterial agent triclosan to oral surfaces (Nabi *et al*, 1989; Gaffar *et al*, 1990, 1994). A study by Kruger *et al* (1996) demonstrated that the concentration of triclosan in plaque biofilm 12 h after brushing the teeth was sufficient to inhibit the growth of bacteria, therefore, retard the return of bad breath. Additionally, the formula was demonstrated to control oral malodor as assessed by a panel of hedonic judges (Sharma *et al*, 1999). The study results indicate that a dentifrice containing 0.3% triclosan/2% PVM/MA copolymer/0.243% sodium fluoride, commercially sold as Colgate® Total® Advanced Fresh™ Gel, is effective in controlling daytime and overnight bad breath for up to 12 h, and that its clinical end points satisfy the proposed ADA Draft Acceptance Program Guidelines for Products Used in the Management of Oral Malodor.

In conclusion, the results of this double-blind clinical study clearly indicate that a dentifrice containing triclosan/copolymer/sodium fluoride provides effective control of oral malodor for up to 12 h.

Acknowledgment

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